

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS	:	
CORPORATION, NOVARTIS AG,	:	
NOVARTIS PHARMA AG, and	:	
NOVARTIS INTERNATIONAL	:	
PHARMACEUTICAL LTD.,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	Civil Action No. 00-800-JJF
	:	
EON LABS MANUFACTURING, INC.,	:	
	:	
Defendant.	:	

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**MEMORANDUM OPINION**

December 9, 2002

Wilmington, Delaware

**Farnan, District Judge.**

Pending before the Court is Defendant's Motion For Partial Summary Judgment Dismissing Plaintiffs' Claims That Defendant Has Induced And Contributed To Infringement Of The Suit Patent (D.I. 268). The Court issued its claim construction in this matter and invited the parties to submit supplemental briefing on the Motion. After reviewing the supplemental briefing, the Court reserved decision on the instant Motion. (D.I. 394). Shortly thereafter, the Court informed the parties that trial in this action would be canceled, and the Court would be entering summary judgment on the papers submitted. For the reasons discussed, the Court will grant Defendant's Motion For Partial Summary Judgment Dismissing Plaintiffs' Claims That Defendant Has Induced And Contributed To Infringement Of The Suit Patent.

**BACKGROUND**

**I. Procedural Background**

This action was brought by Plaintiffs, Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG and Novartis International Pharmaceutical Ltd. (collectively, "Novartis") against Defendant, Eon Labs Manufacturing, Inc. ("Eon") for infringement of U.S. Patent No. 5,389,382 (the "'382 Patent"). Eon filed an Answer and Counterclaim to the Complaint denying infringement, asserting the affirmative defenses of patent invalidity and non-infringement, and seeking a declaratory

judgment that the '382 Patent was invalid, unenforceable and not infringed. Discovery ensued, and Eon subsequently filed summary judgment motions contending that (1) Eon does not actively induce or contribute to infringement of the '382 Patent in patients' stomachs; and (2) Eon does not directly infringe the '382 Patent when it performs the ethanol content test. With regard to the second issue, Novartis sought only injunctive relief, and Eon agreed not to perform any of the alleged infringing tests in the future. Based on Eon's position and without addressing the underlying claim of whether the ethanol content tests directly infringed the '382 Patent, the Court enjoined Eon from conducting the alleged infringing tests in the future. (D.I. 392). This Memorandum Opinion constitutes the Court's decision on the remaining issue raised by Eon for resolution on summary judgment.

## **II. The '382 Patent Generally**

The '382 Patent relates to hydrosol compositions of pharmaceutically active agents, including the immunosuppressive drug cyclosporin, which are suspended or re-suspendable in an aqueous medium. The claimed hydrosol comprises solid active agent particles and behaves, insofar as pharmacological activity is concerned, as an injectable solution when it is suspended in water. ('382 Patent, col. 1, ll. 48-51). The '382 Patent also provides a process for creating the hydrosol composition. ('382 Patent, col. 6, ll. 1-64). In this action, Novartis asserts

Claims 1, 2, 8 and 9 of the '382 Patent against Eon. Of the asserted claims, Claim 1 is the only independent claim. Claim 1 reads as follows:

A hydrosol which comprises solid particles of a cyclosporin and a stabilizer which maintains the size distribution of said particles, wherein said cyclosporin has a water solubility below 0.5 grams per 100 milliliters, and said particles have a weight ratio of cyclosporin to water of about 1:300 to about 1:1500 and a weight ratio of cyclosporin to said stabilizer of about 1:1 to about 1:50.

('382 Patent, col. 9, ll. 21-28).

Following a Markman hearing, the Court issued its claim construction on the disputed terms in Claim 1 of the '382 Patent. Based on this claim construction, the Court will grant Eon's motion for partial summary judgment that it does not actively induce or contribute to infringement of the '382 Patent in the stomachs of patients who ingest its cyclosporin capsules.<sup>1</sup>

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<sup>1</sup> Eon also contends that it is entitled to partial summary judgment based on (1) its reliance on the advice of counsel, (2) Novartis' failure to produce evidence establishing that Eon knew or could have known that direct infringement would result in the stomachs of patients who ingest its capsules, (3) Novartis' failure to produce evidence establishing that Eon intended to cause direct infringement, and (4) the existence of substantial non-infringing uses for Eon's product. Reliance on the advice of counsel, though relevant, is not necessarily dispositive of Novartis' claims of inducement of infringement and contributory infringement. See e.g. CVI/Beta Ventures, Inc. v. Tura LP, 905 F. Supp. 1171 (E.D.N.Y. 1995); Symbol Technologies, Inc. v Metrologic Instruments, Inc., 771 F. Supp. 1390, 1405 (D.N.J. 1991). Further, the Court has concluded that its claim construction is dispositive of the pending issues in this case, and therefore, the Court declines to address the other grounds raised by Eon for summary judgment.

## DISCUSSION

### I. Standard of Review

Pursuant to Rule 56(c) of the Federal Rules of Civil Procedure a party is entitled to summary judgment if a court determines from its examination of "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any," that there are no genuine issues of material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). In determining whether there is a triable dispute of material fact, a court must review all of the evidence and construe all inferences in the light most favorable to the non-moving party. Goodman v. Mead Johnson & Co., 534 F.2d 566, 573 (3d Cir. 1976). However, a court should not make credibility determinations or weigh the evidence. Reeves v. Sanderson Plumbing Prods., Inc., 120 S. Ct. 2097, 2110 (2000). Thus, to properly consider all of the evidence without making credibility determinations or weighing the evidence the "court should give credence to the evidence favoring the [non-movant] as well as that 'evidence supporting the moving party that is uncontradicted and unimpeached, at least to the extent that that evidence comes from disinterested witnesses.'" Id. The moving party bears the burden of proving that no genuine issue of material fact is in dispute. Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 586

n. 10 (1986)).

To defeat a motion for summary judgment, Rule 56(c) requires the non-moving party to:

do more than simply show that there is some metaphysical doubt as to the material facts. . . . In the language of the Rule, the non-moving party must come forward with "specific facts showing that there is a genuine issue for trial." . . . Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is "no genuine issue for trial."

Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 586-87 (1986). Accordingly, a mere scintilla of evidence in support of the non-moving party is insufficient for a court to deny summary judgment. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252 (1986). Rather, a genuine issue for trial exists only if the record taken as a whole could lead a rational person to conclude that the position of the person with the burden of proof on the disputed issue is correct. Horowitz v. Federal Kemper Life Assurance Co., 57 F.3d 300, 302 n.1 (3d Cir. 1995) (citations omitted). Thus, if the non-moving party fails to make a sufficient showing on an essential element of his or her case to which he or she has the burden of proof, the moving party is entitled to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).

## **II. The Law of Infringement**

In relevant part, 35 U.S.C. § 271(b) and (c) provide:

(b) Whoever actively induces infringement of a patent

shall be liable as an infringer.

(c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture or combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

35 U.S.C. § 271(b), (c).

It is well-established that there cannot be inducement of infringement or contributory infringement absent direct infringement. Carborundum Co. v. Molten Metal Equipment Innovations, Inc., 72 F.3d 872, 876 n.4 (Fed. Cir. 1995). As such, a claim for inducement of infringement and contributory infringement is dependent upon proof of direct infringement. Epcon Gas Systems, Inc. v. Bauer Compressor, Inc., 279 F.3d 1022, 1033 (Fed. Cir. 2002).

A patent is directly infringed when a person "without authority makes, uses or sells any patented invention, within the United States during the term of the patent...." 35 U.S.C. § 271(a). A patent owner may prove infringement under either of two theories: literal infringement or the doctrine of equivalents. Literal infringement occurs where each element of at least one claim of the patent is found in the alleged infringer's product. Panduit Corp. v. Dennison Mfg. Co., 836

F.2d 1329, 1330 n. 1 (Fed. Cir. 1987); Robert L. Harmon, Patents and the Federal Circuit 195 & n. 31 (3d ed.1994). For there to be infringement under the doctrine of equivalents, the accused product or process must embody every element of a claim, either literally or by an equivalent. Warner-Jenkinson, 520 U.S. 17, 41 (1997). Thus, the mere showing that an accused device is equivalent overall to the claimed invention is insufficient to establish infringement under the doctrine of equivalents. In determining whether a patent has been infringed, the patent owner has the burden of proof and must meet its burden by a preponderance of the evidence. SmithKline Diagnostics, Inc. v. Helena Lab. Corp., 859 F.2d 878, 889 (Fed. Cir. 1988) (citations omitted).

Infringement is a two step inquiry. Step one requires a court to construe the disputed terms of the patent at issue. Step two requires the court to compare the accused products with the properly construed claims of the patent. Having construed the disputed terms of the '382 Patent, the Court will proceed to a comparison of the accused product with the claims of the patent as construed by the Court to determine if Novartis has offered sufficient evidence to withstand summary judgment on the question of direct infringement of the '382 Patent in patients' stomachs.

**III. Whether Eon Is Entitled To Summary Judgment Based On The Court's Claim Construction That It Does Not Actively Induce**

**Or Contribute To Infringement Of The '382 Patent In Patients' Stomachs**

In claiming that Eon is liable for inducement of infringement or contributory infringement, Novartis contends that patients who ingest Eon's product form the claimed composition in their stomachs, thereby infringing the '382 Patent and that Eon induces and contributes to the infringement by these patients. Novartis does not contend that Eon's product infringes before this dilution in the patients' stomachs.

Eon contends that summary judgment is warranted, because the Court's claim construction of the term "hydrosol" precludes Novartis from establishing direct infringement. The Court construed the term "hydrosol" to mean:

(a) a synthetic pharmaceutical preparation, i.e. it does not encompass a dispersion of solid particles of cyclosporin which only forms in the stomach of a patient; and

(b) all the cyclosporin is in solid particle form and not in solution, excepting for a very small amount of cyclosporin which the water in the hydrosol can solubilize.

(D.I. 373 at 6). The Court agrees with Eon and concludes that both aspects of the Court's definition preclude Novartis from establishing its infringement claim.

Explaining its conclusion with regard to the first part of the definition of the term "hydrosol," the Court stated "that the specification and prosecution history require that the term 'hydrosol' be limited in scope to synthetic pharmaceutical

preparations which are not formed within the stomach of a patient." (D.I. 373 at 5) (emphasis added). However, as the Court previously stated, Novartis' infringement argument is based on its allegation that patients who ingest Eon's product form the claimed composition in their stomachs. The Court's claim construction excludes compositions which form in patients' stomachs and limits the term "hydrosol" to "synthetic preparations" which are not formed within the stomach of a patient.<sup>2</sup> Indeed, Novartis does not challenge Eon's assertions that there is no hydrosol present in Eon's capsules and that the allegedly infringing hydrosol only forms in the patient's stomach after the capsules rupture following ingestion. Because the Court's claim construction refers only to synthetic pharmaceutical preparations and not those that form in the stomach of a patient, Novartis cannot establish direct infringement of its patent under the theory of literal infringement.

Novartis also advances an infringement argument under the

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<sup>2</sup> Novartis argues that the use of the word "only" in the Court's definition of the term "hydrosol" reinstates the possibility that the alleged infringing hydrosol could be formed in the patient's stomach. Novartis' argument ignores the context of the Court's claim construction. As the Court explained in its claim construction opinion, the specification and the prosecution history "do[] not support an interpretation regarding hydrosols formed naturally upon ingestion." (D.I. 373 at 5). Further, Novartis' argument eviscerates the first portion of the definition which limits the term hydrosol to "synthetic preparations."

doctrine of equivalents. Specifically, Novartis contends that "a hydrosol formed outside the body of a patient is equivalent to one formed in the patient's stomach and therefore, the hydrosol made in the patient's stomach infringes under the doctrine of equivalents." (D.I. 379 at 5). Novartis contends that it can establish infringement under the doctrine of equivalents at trial based upon the experiments of its expert witness, Professor Hem. According to Professor Hem, the experiments he conducted in vitro (i.e. outside of the body) "accurately simulate those found in patients," such that the results of Professor Hem's experiments "would have been no different had they been conducted in vivo in an actual patient." (D.I. 379, Exh. 1 at ¶¶ 27, 29). Based on Professor Hem's assertions, Novartis contends that what happened in Professor Hem's in vitro experiments is equivalent to what happens in the stomach of a patient who ingests Eon's capsules.

As a matter of law, the Court concludes that Novartis cannot sustain its doctrine of equivalents infringement argument. First, it appears to the Court that throughout this litigation Novartis relied only upon a theory of literal infringement and not upon an equivalents theory. As such, it is questionable whether Novartis should even be permitted to pursue a different infringement theory at such a late stage in this litigation.

However, even if Novartis is permitted to advance its equivalents theory, the Court concludes that Eon is entitled to

summary judgment. Novartis' claim of infringement against Eon is based on the alleged formation of a hydrosol in the stomach of patients who ingest Eon's capsules. That Novartis' experts may be able to replicate this hydrosol in a test tube is irrelevant to this claim. The doctrine of equivalents requires the plaintiff to show that each element of a claim is present literally or equivalently in the accused product. By its argument, Novartis attempts to compare the claims of the '382 Patent to the work of its expert, rather than to the act of infringement that it accuses Eon of, i.e. forming hydrosols in the stomachs of patients who ingest its capsules.

Further, the Federal Circuit has recognized that the doctrine of equivalents cannot be used to eviscerate a claim limitation. See e.g. Dolly, Inc. v. Spalding & Evenflo Companies, Inc., 16 F.3d 394, 398 (Fed. Cir. 1994); Conopco, Inc. v. May Department Stores Co., 46 F.3d 1556, 1562 (Fed. Cir. 1994). Using an equivalents theory in this case would reinstate the possibility that the '382 Patent covers hydrosols which form in the stomachs of patients. As the Court's claim construction makes clear, the '382 Patent does not cover hydrosols which form naturally in the stomachs of patients.

As for the second prong of the Court's definition of the term "hydrosol," the Court likewise concludes the Court's claim construction precludes Novartis from establishing direct

infringement of the '382 Patent. In defining the term "hydrosol," the Court concluded that "all the cyclosporin is in solid particle form and not in solution, excepting for a very small amount of cyclosporin which the water in the hydrosol can solubilize." Novartis does not dispute that when Eon's cyclosporin capsules are dispersed in an aqueous medium such as the stomach, approximately 50% of the cyclosporin remains in solution. However, Novartis contends that all of cyclosporin in the hydrosol remains in solid particle form, irrespective of what happens to the rest of the cyclosporin in Eon's capsule. Stated another way, Novartis contends that "[t]he fact that some of that cyclosporin may be in solution, does not change the fact that the cyclosporin that is in the 'hydrosol' is, by definition, all in solid particle form . . . ." (D.I. 379 at 7) (emphasis added).

The Court is not persuaded by Novartis' argument. Throughout this litigation, Novartis argued that a hydrosol is a suspension of solid particles in an aqueous (water-containing) medium. Indeed, the Court's construction of the term "hydrosol" presumes that water is present in the hydrosol, because the Court recognized that with the exception of "a very small amount of cyclosporin which the water in the hydrosol can solubilize," the remainder of the cyclosporin would be in solid particle form. (D.I. 373 at 6) (emphasis added). Further, Claim 1 of the '382 Patent requires a certain weight ratio of solid cyclosporin

particles to water, thereby recognizing that water is necessarily part of the hydrosol. However, Novartis' argument attempts to divorce water from the claimed hydrosol such that the claimed hydrosol consists only of solid particles without any solubilized cyclosporin. Novartis' argument undercuts the claim language and the Court's construction of the term "hydrosol," both of which recognize that a small amount of cyclosporin is solubilized in the water in the hydrosol.

In this case, Novartis does not contest Eon's assertion that approximately 50% of the cyclosporin remains in solution when Eon's cyclosporin capsules are ingested. Novartis does not argue that this is "a very small amount" as required by the claim language, and the Court is not persuaded that this is a very small amount. Thus, the Court concludes that the term "hydrosol" as construed by the Court is absent from the claimed product literally or equivalently when it is in a patient's stomach.<sup>3</sup>

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<sup>3</sup> Novartis raises its doctrine of equivalents argument in a footnote. Without any explanation or evidence, Novartis contends that: "Whether there is a dual system of a hydrosol together with solubilized cyclosporin or a hydrosol alone it makes no difference. The hydrosol and the solid particles therein provide the same function, in the same way, to achieve the same results in both systems." (D.I. 379 at 8 n.4). Novartis' equivalents argument as to the second prong of the definition of the term "hydrosol" suffers from the same defects as its equivalents argument under the first prong of the definition of the term "hydrosol," and therefore, the Court concludes that Novartis cannot establish infringement under the doctrine of equivalents. In addition, the Court concludes that Novartis has not offered any evidence as a factual matter to sustain its claim of infringement under the doctrine of

In sum, the Court concludes that Novartis cannot establish infringement literally or under the doctrine of equivalents. The accused product as ingested by a patient simply does not contain the claimed "hydrosol" as that term is defined by the Court. Having failed to establish direct infringement of independent Claim 1 of the '382 Patent, Novartis cannot establish infringement of dependent Claims 2, 8, and 9 of the '382 Patent. Because Novartis cannot establish direct infringement of the '382 Patent in the stomachs of patients, it cannot establish that Eon actively induces or contributes to infringement of the '382 Patent in the stomachs of patients. Accordingly, the Court will grant partial summary judgment in favor of Eon on this issue.

#### **CONCLUSION**

For the reasons discussed, the Court will grant Defendant's Motion For Partial Summary Judgment Dismissing Plaintiffs' Claims That Defendant Has Induced And Contributed To Infringement Of The Suit Patent (D.I. 268).

An appropriate Order will be entered.

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equivalents.

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FOR THE DISTRICT OF DELAWARE

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NOVARTIS PHARMA AG, and	:	
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Plaintiffs,	:	
	:	
v.	:	Civil Action No. 00-800-JJF
	:	
EON LABS MANUFACTURING, INC.,	:	
	:	
Defendant.	:	

**ORDER**

At Wilmington, this 9th day of December 2002, for the reasons discussed in the Memorandum Opinion issued this date;

IT IS HEREBY ORDERED that Defendant's Motion For Partial Summary Judgment Dismissing Plaintiffs' Claims That Defendant Has Induced And Contributed To Infringement Of The Suit Patent (D.I. 268) is GRANTED.

JOSEPH J. FARNAN, JR.  
UNITED STATES DISTRICT JUDGE